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MAIL STOP - PCT
Attorney Docket No.: 27193U
Date: June 15, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Art Unit: Unknown

LIPPERT, et al.

Examiner: Unknown

Appl. No.: 10/568,417

Filed: February 14, 2006

Intl. Appl. No.: PCT/EP2004/051841

Intl. Filing Date: August 19, 2004

For: **PHARMACEUTICAL PRODUCT FOR INJECTION**

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450


Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- 1) Submission of Documents to Supplement Filing Documents under 35 USC 371;
- 2) PCT/IB/373 (International Preliminary Report on Patentability);
- 3) PCT/ISA/237 (Written Opinion of the International Searching Authority).

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account Number 14-0112.

Respectfully submitted,
NATH & ASSOCIATES PLLC



Gary M. Nath, Reg. No. 26,965
Sheldon M. McGee, Reg. No. 50,454
Customer No. 34375

GMN/SMM/1e



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SUBMISSION OF DOCUMENTS
TO SUPPLEMENT FILING DOCUMENTS UNDER 35 USC 371

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450


Sir:

In order to supplement the filing documents for the national phase filing Under USC 371 commenced on **February 14, 2006**, applicant now submits the following documents:

- 1) PCT/IB/373 (International Preliminary Report on Patentability);
- 2) PCT/ISA/237 (Written Opinion of the International Searching Authority).

Please charge any deficiency or credit any overpayment to our Deposit Account Number 14-0112.

Respectfully submitted,
NATH & ASSOCIATES PLLC



Gary M. Nath, Reg. No. 26,965
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 1214WOORD01	FOR FURTHER ACTION See item 4 below	
International application No. PCT/EP2004/051841	International filing date (<i>day/month/year</i>) 19 August 2004 (19.08.2004)	Priority date (<i>day/month/year</i>) 21 August 2003 (21.08.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ALTANA PHARMA AG		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|--|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input checked="" type="checkbox"/> Box No. II | Priority |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland		Date of issuance of this report 21 February 2006 (21.02.2006)
Facsimile No. +41 22 740 14 35		Authorized officer Agnes Wittmann-Regis
Form PCT/IB/373 (January 2004)		Telephone No. +41 22 338 89 70

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 02 DEC 2004

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To:

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/051841

International filing date (day/month/year)
19.08.2004

Priority date (day/month/year)
21.08.2003

International Patent Classification (IPC) or both national classification and IPC
A61K31/44, A61J3/00

Applicant
ALTANA PHARMA AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Cattell, James

Telephone No. +49 89 2399-8468



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/051841

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/051841

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	9-12, 18
	No: Claims	1-8, 13, 14, 15, 16, 17, 19, 20
Inventive step (IS)	Yes: Claims	
	No: Claims	1-20
Industrial applicability (IA)	Yes: Claims	1-20
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/051841

Re Item V.

- 1 The following documents are referred to in this communication:
D1 : "Section 3 - Summary of Product Characteristics" PROTIUM -PRODUCT SUMMARY. ISSUED BY BYK GOLDEN , DE, January 2000 (2000-01), XP002163617
D2 : US 2003/003058 A1 (LINDER RUDOLF ET AL) 2 January 2003 (2003-01-02)
D3 : LEITNER ET AL: "Visuelle dokumentation der Stabilität der intravenösen Lösungen von Omeprazol und Pantaprazol" WIEN.MED.WSCHR, vol. 152, 2002, pages 568-573, XP001204762
- 2). D1 discloses that the marketed product "Protium" is in freeze dried form in a glass vial with an aluminum cap and rubber stopper. Zinc is not present. This disclosure falls within the scope of claims 1, 2, 3, 5, 7,8, 13, 17, 19, and 20 under Article 33(2) PCT.
- 3). Both D2 and D3 disclose proton pumps in solution for injection. No zinc is disclosed. These documents therefore fall within the scope of claims 1-8, 13, 14, 15, 17, 19 and 20 under Article 33(2) PCT.
- 4). The subject-matter of the remaining claims would appear to rely on the use of known techniques. These claims therefore cannot be regarded as inventive under Article 33(3) PCT.